

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BIOGEN INTERNATIONAL GMBH and)
BIOGEN MA INC.,)
)
Plaintiffs,)
)
) Civil Action No.: 17-cv-00116-IMK
v.)
MYLAN PHARMACEUTICALS INC.,)
)
Defendant.)
)
)

JOINT STATUS REPORT

Plaintiffs Biogen International GmbH and Biogen MA Inc. (“Biogen”) and Defendant Mylan Pharmaceuticals Inc. (“Mylan”), by their undersigned attorneys, respectfully submit this Status Report as required by the Court’s *Order to File Status Report*, entered October 3, 2018. (See D.I. 129).

I. JOINT CASE STATUS SUMMARY

Biogen instituted this action against Mylan on June 30, 2017, alleging infringement of U.S. Patent Nos. 6,509,376 (“the ’376 patent”), 7,320,999 (“the ’999 patent”), 7,619,001 (“the ’001 patent”), 7,803,840 (“the ’840 patent”), 8,759,393 (“the ’393 patent”) and 8,399,514 (“the ’514 patent”), after receiving notice from Mylan that it had filed Abbreviated New Drug Application (“ANDA”) No. 210531 seeking approval for a generic version of Tecfidera®. (D.I. 1.)

Biogen has served initial infringement contentions, and Mylan has served initial invalidity contentions, as well as first amended invalidity contentions.

The parties have completed claim construction proceedings, in which they stipulated to several constructions. D.I. 102.

The parties extended, with approval from the Court, the due date for the substantial completion of document production from July 30, 2018 to September 14, 2018 and the close of fact discovery from October 1, 2018 to October 31, 2018. (See D.I. 111, 118.). Fact discovery is therefore scheduled to close on October 31, 2018. D.I. 118.

On July 13, 2018, Mylan filed a Petition before the United States Patent Trials and Appeal Board (“PTAB”) seeking *inter partes* review (“IPR”) of Biogen’s ’514 patent. Biogen’s Patent Owner’s Preliminary Response is due on November 8, 2018, and pursuant to the PTAB’s statutorily mandated deadlines, the PTAB will issue its decision as to whether to institute Mylan’s IPR petition by February 8, 2019.

II. PARTIES SEPARATE STATEMENTS REGARDING STATUS AND ISSUES

A. BIOGEN SEEKS COORDINATION OF DEPOSITIONS BETWEEN MYLAN AND THE DELAWARE DEFENDANTS

Biogen simultaneously filed twenty-five related Hatch-Waxman actions in the District Court for the District of Delaware (the “Delaware actions”).¹ The Delaware actions have all

¹ *Biogen International GmbH and Biogen MA Inc. v. Amneal Pharmaceuticals LLC*, C.A. No. 17-cv-823 (D. Del., filed June 26, 2017); *Biogen International GmbH and Biogen MA Inc. v. Aurobindo Pharma U.S.A., Inc. and Aurobindo Pharma USA LLC*, C.A. No. 17-cv-824 (D. Del., filed June 26, 2017); *Biogen International GmbH and Biogen MA Inc. v. Hetero USA Inc., Hetero Labs Limited Unit-III and Hetero Labs Limited*, C.A. No. 17-cv-825 (D. Del., filed June 26, 2017); *Biogen MA Inc. v. Impax Laboratories, Inc.*, C.A. No. 17-cv-826 (D. Del., filed June 26, 2017); *Biogen MA Inc. v. Princeton Pharmaceutical Inc.*, C.A. No. 17-cv-827 (D. Del., filed June 26, 2017); *Biogen MA Inc. v. Slayback Pharma LLC and Slayback Pharma India LLP*, C.A. No. 17-cv-828 (D. Del., filed June 26, 2017); *Biogen International GmbH and Biogen MA Inc. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 17-cv-829 (D. Del., filed June 26, 2017); *Biogen MA Inc. v. MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc.*, C.A. No. 17-cv-845 (D. Del., filed June 28, 2017); *Biogen MA Inc. v. Graviti Pharmaceuticals Pvt. Ltd. and Graviti Pharmaceuticals Inc.*, C.A. No. 17-cv-846 (D. Del., filed June 28, 2017); *Biogen MA Inc. v. Shilpa Medicare Limited*, C.A. No. 17-cv-847 (D. Del., filed June 28, 2017); *Biogen MA Inc. v. Sun Pharma Global FZE*, C.A. No. 17-cv-848 (D. Del., filed June 28, 2017); *Biogen MA Inc. v. Windlas Healthcare, Pvt. Ltd.*, C.A. No. 17-cv-849 (D. Del., filed June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. Alkem Laboratories Ltd. and S&B Pharma, Inc.*, C.A. No. 17-cv-850 (D. Del., filed

been assigned to Chief Judge Stark and have been consolidated. Substantial completion of document production in the Delaware actions was concluded on September 28, 2018. As of the filing of this Joint Status Report, the actions involving nine Defendants in the Delaware actions have been stayed and there are thirteen Defendants currently actively litigating the action.

As Biogen addressed during the November 1, 2017, Scheduling Conference (D.I. 55 at 7-8), and again during the January 22, 2018 Status Conference (D.I. 71 at 14-15), Biogen believes that coordination of depositions between Mylan and the Defendants in the Delaware actions is warranted to minimize any inconvenience to witnesses, many of whom are not employed by Biogen, and to conserve the parties' resources. This Court previously commented on the appropriateness of coordinating depositions between the two actions. (*See* D.I. 55 at 16:21-17:4.)

To this end, Biogen sent a letter to Mylan and the Defendants in the Delaware action on October 5, 2018, explaining that "coordination of depositions is the most efficient and least inconvenient means for Defendants to obtain the information they seek from these individuals.

June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. Cipla Limited and Cipla USA Inc.*, C.A. No. 17-cv-851 (D. Del., filed June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA*, C.A. No. 17-cv-852 (D. Del., filed June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. Lupin Atlantis Holdings SA and Lupin Inc.*, C.A. No. 17-cv-853 (D. Del., filed June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.*, C.A. No. 17-cv-854 (D. Del., filed June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. Pharmathen S.A.*, C.A. No. 17-cv-855 (D. Del., filed June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. TWi Pharmaceuticals, Inc. and TWi Pharmaceuticals USA, Inc.*, C.A. No. 17-cv-856 (D. Del., filed June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc.*, C.A. No. 17-cv-857 (D. Del., filed June 28, 2017); *Biogen International GmbH and Biogen MA Inc. v. Accord Healthcare Inc.*, C.A. No. 17-cv-872 (D. Del., filed June 30, 2017); *Biogen International GmbH and Biogen MA Inc. v. Par Pharmaceutical, Inc.*, C.A. No. 17-cv-873 (D. Del., filed June 30, 2017); *Biogen International GmbH and Biogen MA Inc. v. Sandoz Inc.*, C.A. No. 17-cv-874 (D. Del., filed June 30, 2017); *Biogen International GmbH and Biogen MA Inc. v. Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd.*, C.A. No. 17-cv-875 (D. Del., filed June 30, 2017); *Biogen International GmbH and Biogen MA Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 17-cv-954 (D. Del., filed July 14, 2017).

Moreover, and as you are aware, the named inventors of the asserted patents are not Biogen employees and while they are willing to cooperate in appearing for a deposition, Biogen does not control their schedules. As such, Biogen seeks Defendants' cooperation in coordinating their efforts in depositions." (Ex. A.) Mylan, as indicated below, expressed a willingness to coordinate depositions with the Defendants in Delaware, with the condition that such depositions be completed by the end of November. (Ex. B.) While the Defendants in Delaware contend this issue was never before raised, they are incorrect, as deposition coordination was discuss during the parties' meet-and-confers addressing the Delaware schedule. Nonetheless, the Defendants in Delaware expressed a willingness to coordinate depositions with Mylan if they were to begin in January 2019. (Ex. C at 2.) In response, on October 12, 2018, Biogen sent a letter to Mylan and the Defendants in Delaware seeking a compromise, stating: "To compromise, and minimize the burden on witnesses, Biogen requests that depositions of non-Biogen employees, including inventors, are scheduled so they are completed by the end of December 2018. This would provide Delaware Defendants additional time to review documents, while at the same time not significantly altering the West Virginia schedule." (Ex. D.) Completing depositions by the end of December will require a modest extension of the expert discovery schedule, but sufficient time exists within the schedule such that the February 2020 trial date will not need to be moved.

Biogen believes that coordination of depositions of non-Biogen employees, including inventors, will be more convenient for the witnesses, avoid duplicative discovery, and minimize costs to the parties. Further, Biogen is in contact with each of the witnesses noticed by Mylan and is working to obtain dates for their depositions. Several of these witnesses are not, or no longer, Biogen employees and thus Biogen cannot dictate their schedule. Biogen, however, is coordinating with non-Biogen employees who live outside the U.S. to travel to the U.S. for their

depositions such that Mylan and the Delaware Defendants do not need to travel internationally. And while Mylan has issued notices of intent to subpoena two witnesses, Biogen is in contact with those witnesses and believes that a subpoena will not be needed. Biogen will continue to work with Mylan and the Delaware Defendants on this issue and will provide an update to the Court during the October 19, 2018 Status Conference.

The current Scheduling Order contemplates 7 hours of deposition time for all fact witnesses, including inventors. (*See D.I. 56 at ¶9.*) To accommodate coordination, Biogen has offered to enlarge the time period for each deposition, providing Mylan and the Delaware Defendants 11 hours of deposition time for each inventor and 8 hours of deposition time for each fact witness.

With respect to Patent Term Extension (“PTE”), Biogen received four Notices of Final Determinations from the PTO on September 26, 2018, and must elect a single patent it will select for PTE within 30 days of that date. Biogen will make such an election within that time frame. Biogen believes that once election is made, it will be able to come to an agreement with Mylan as to the disposition of the three patents not selected for PTE and Court intervention is not needed at this time.

B. MYLAN’S STATEMENT OF STATUS AND ISSUES

Mylan has for many weeks been seeking to take depositions and conclude fact discovery within the existing deadlines. Biogen has generally failed to respond to deposition notices or requests, and generally obstructed the goal of timely completion. In part, Biogen asserts that the Court’s schedule cannot be met, and that the delays are needed to allow deposition coordination with the defendants in the Delaware actions involving some of the same patents. The Court has previously repeatedly rejected Biogen’s requests for coordination.

After filing its complaint, Biogen sought a stay of this action or, in the alternative, requested that the Court order Mylan to coordinate discovery with the Delaware action. Mylan opposed both motions. During the initial scheduling conference and a later status conference, this Court denied Biogen's motion to stay and denied Biogen's motion to coordinate to the extent coordination would cause a conflict with this Court's Scheduling Order. Tr. at 19:18-20:1, Jan. 22, 2018 ("Biogen's motion [requesting] a stay in this action [is denied] and to the extent Biogen is seeking to coordinate discovery and claim construction with the Delaware actions, the Court's ruling is to deny that request to the extent it conflicts with the schedule that's been entered in this case.").

Notwithstanding the prior decision of the Court, and the actions of Biogen, Mylan has proposed a compromise. Mylan has agreed to Biogen's request to depose the named inventors on the patents-in-suit outside of the period set for fact discovery, on certain dates in November 2018, if the parties and the Court agree that Mylan may seek any additional discovery related to or arising from those depositions if needed, if Biogen agrees to produce all of its witnesses by the end of November, and the parties agree to, and if the Court approves, a modest extension of the expert discovery deadlines. *See Exhibit B* (10/10/2018 Greb to Sukduang).

Mylan does not object to the Delaware defendants attending the inventor depositions on the dates identified by Biogen and has offered to coordinate to the extent that the Delaware defendants are willing to do so, the parties are able to cooperate, and the depositions proceed on the November dates. *Id.* However, the Delaware defendants have indicated they are not willing to proceed with depositions until January 2019 at the earliest, well past the fact discovery period set in this case. *See Exhibit C* (10/10/2018 McNair to Sukduang). The Delaware defendants

have also stated that Biogen has not previously raised coordination with them or with the Delaware Court. *Id.* Given this, it appears that coordination may not be possible.

Mylan received Biogen's letter dated 10/12/2018, attached as Exhibit D, at 12:50 pm EST. Mylan plans to take the depositions of the inventors on the offered November 2018 dates. Mylan will review Biogen's letter and respond.

Mylan has requested that Biogen provide or identify in its production any agreements it has with inventors on the patents-in-suit requiring their cooperation in litigation. As of this time, Biogen has not responded.

Additionally, Mylan respectfully requests discussion at the status conference of deposition dates for the other fact depositions that Mylan has noticed. Those depositions include a 30(b)(6) deposition of Biogen, and the depositions of Carmen Bozic, Cara Lansden, Tammy Sarnelli, and Katherine Dawson. Several of these fact witnesses may be former Biogen employees. Mylan requested that Biogen inform Mylan whether Biogen will be producing these witnesses for deposition or whether Mylan will need to issue subpoenas. Having not heard from Biogen, Mylan has issued subpoenas to Cara Lansden and Tammy Sarnelli. Mylan is awaiting dates from Biogen for Katherine Dawson, Carmen Bozic, and any 30(b)(6) designees.

Also, Mylan respectfully requests discussion of the expiration date(s) for several of the patents-in-suit. The '393 patent has expired. It is Mylan's position that this patent should be dismissed from this case. Also, Biogen previously applied for regulatory patent term extension ("PTE") on the '376, '999, '001, and '840 patents. Under the relevant statutes, PTE can ultimately be applied to only one of those four patents. Biogen must elect which patent it will apply PTE to by no later than October 26, 2018. On or before that date Biogen is required to inform the U.S. Patent and Trademark Office of its election. The other three patents that Biogen

does not elect will then expire prior to the expiration of the 30-month regulatory stay of approval of Mylan's ANDA at issue in this case. It is therefore Mylan's position that the patents to which PTE is not applied should be dismissed from this case. Dismissing four patents that are either already expired or will expire before the 30-month stay runs its course will significantly streamline the future conduct of this case, and the associated burden on the Court and the parties.

October 12, 2018

By: /s/ James F. Companion

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CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of October 2018, I filed the foregoing "Joint Status Report" with the Clerk of the Court using the CM/ECF system of the Court which will cause notice thereof to be served on the following counsel of record via email:

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Dated this 12th Day of October 2018.

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